



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

55180d

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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January 14, 2005

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Dennis Gay
Chief Executive Officer
Basic Research, LLC
5742 W. Harold Gatty Drive
Salt Lake City, Utah 84116

Ref#: Den 05-06

Dear Mr. Gay:

This letter is in reference to your firm's marketing and distribution of StriVectin-SD, StriVectin-SD Eye Cream, and Dermalin-APg. The Food and Drug Administration (FDA) has reviewed the labeling for these products, including your websites at www.kleinbecker.com and www.striVectin.com. FDA has determined that your products StriVectin-SD, StriVectin-SD Eye Cream, and Dermalin-APg are promoted with claims that cause the products to be drugs under section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 321(g)(1)(C)).

As defined in section 201(g)(1)(C) of the Act, the term "drug" means articles (other than food) intended to affect the structure or function of the body. The labeling for your products includes several claims that demonstrate that these products are intended to affect the structure or function of the body (structure/function claims). Examples of some of the claims observed in your products' labeling include:

StriVectin-SD:

- "Intensive Concentrate For Existing Stretch Marks (Striae Distensae)"
- "Clinically Proven to Dramatically Reduce the Appearance of Existing Stretch Mark Length, Depth, Texture, and Discoloration"
- "Optimum Glycosaminoglycan and Collagen Synthesis"
- "Better than Botox®?"
- "A stretch-mark reducing emulsion ... to diminish fine lines, wrinkles and crow's feet."

- “[S]uperior wrinkle-reducing properties of a patented oligo-peptide (called Pal-KTTKS) ... on ‘photo-aged skin’ [A] key ingredient in the StriVectin cream.”
- “[S]ignificant improvement’ in wrinkle depth, length, wrinkle volume”
- “Pal-KTTKS solution’s effectiveness at reducing the appearance of fine lines and wrinkles...”
- “StriVectin-SD actually increases the synthesis of new collagen (StriVectin-SD increases collagen I synthesis by 117%, increases collagen IV synthesis by 357%, and increases glycosaminoglycan synthesis by 267%), making your skin thicker and firmer.”
“StriVectin-SD’s clinically proven, proprietary compounds will produce a visible reduction in actual length, size, depth, feel, color, and rough texture of your existing wrinkles and/or stretch marks.”
- “[R]educe wrinkles by as much as 68%, ... and reduce the actual length, depth, volume, and surface area of stretch marks/wrinkles.”
“Q: Can StriVectin-SD® help with acne scars and other types of scarring?
A: Yes.... StriVectin-SD users have reported improvement in acne scars, burn scars, chicken pox marks, scars from old injuries, etc.”
- “93% of the subjects tested saw a dramatic difference in the depth, length, feel, color, and texture of stretch marks.”
“Repair Existing Stretch Marks”
- “[C]linical observations further document the independent active StriVectin-SD isolates dramatically:
 - Decreased the actual length of striae (stretch marks)
 - Decreased the depth of indented surfaces
 - Increased smooth surfaces
 - Increased skin thickness
 - Increased skin firmness
 - Increased stimulation of collagen synthesis
 - Corrected irregularities in skin coloration”“StriVectin-SD: The Most Effective Stretch Mark Repair Compound Ever Developed”
- “[P]roven ability to significantly eradicate the scarred striations of stretch marks....”

StriVectin-SD Eye Cream (www.strivectin.com):

- “Same active formula as the original StriVectin-SD®”
- “StriVectin-SD (the stretch-mark-reducer-turned-anti-wrinkle-phenomenon
- “[S]ignificant decrease in your existing wrinkles or stretch marks”

Dermalin-APg (www.kleinbecker.com):

- “The next-generation transepidermal fat emulsifying gel”
- “Penetrating Gel Emulsifies Fat On Contact”
- “Dissolves Deep-Stored Body Fat Wherever Applied.”
- “[R]educes the accumulation of ‘age-related’ body fat around your waist and abdomen.”
- “[A]ctually reduce the size of ‘saddlebag’ thighs.”

- “[P]enetrate the skin and shrink a woman’s thigh.”
- “[R]eleases fat stores from any problem area. When the fat is released from the back of a woman’s thigh, the dimpled appearance disappears because tension on the connective tissue is reduced as stored ‘depot’ fat is released. However, when the gel is applied to the tummy, waist or hips, a dramatic reduction of stored body fat occurs”
- “Just apply...to your waist or tummy and watch them shrink in size within a matter of days.”
- “Wherever you’ve got those unsightly lumps and bumps, apply Dermalin-APg and they’re gone.”
- “[F]orces the fat out of adipose tissue cells”
- “[O]ne problem area at a time, until you’ve literally melted the fat and molded your body into a more pleasing shape.”

Furthermore, your products are not generally recognized as safe and effective for the above referenced uses and therefore, the products are considered “new drugs” under section 201(p) of the Act. New drugs may not be legally marketed in the U.S. without prior approval from FDA [section 505(a) of the Act].

This letter is not intended to be an all inclusive review of all claims, labeling, or products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action without further notice. The Act provides for the seizure of illegal products, injunctions against the manufacturer and/or distributor of illegal products, and criminal sanctions against persons responsible for causing violations of the Act.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify violations and make corrections to ensure that similar violations will not recur. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Any reply should be sent to the attention of Compliance Officer Shelly L. Maifarth at the above address.

Sincerely,



B. Belinda Collins
District Director